IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNIVERSITY OF MASSACHUSETTS and CARMEL LABORATORIES, LLC, Plaintiffs, v. L'ORÉAL USA, INC., Defendant.	C.A. No. 17-cv-868-CFC-SRF

PLAINTIFFS' RESPONSIVE CONCISE STATEMENT OF FACTS IN FURTHER SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT OF ENABLEMENT

DATED: October 16, 2020

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Plaintiffs' Responses to Defendant's Allegedly Undisputed Facts[1]		
	Allegedly Undisputed Facts	**Plaintiffs' Response**
3	Plaintiffs have disputed that the patents-in-suit are anticipated. (Ex. CC at 29.)	Undisputed.
4	Plaintiffs have disputed that the patents-in-suit are obvious. (Ex. CC at 29.)	Undisputed.
5	Plaintiffs have asserted that none of the prior art identified in L'Oréal USA's invalidity contentions is enabled. (Ex. CC at 29.)	Undisputed that Plaintiffs asserted "none of Defendant's cited references are enabled, including because they disclose concentrations of adenosine contained in compositions, rather than an amount that is applied to the dermal cells; they therefore do not meet the Court's claim construction and do not disclose sufficient information to enable a skilled artisan to apply adenosine in the recited concentration at the dermal cells." Ex. CC, at 29.
6	Plaintiffs' expert, Dr. Bozena Michniak-Kohn, has opined that a single example of an adenosine formulation can be embodied by "tens of thousands" of compositions. (Ex. I, ¶¶ 101, 110.)	Undisputed that Michniak-Kohn opined that, where the prior art provides examples of formulations leaving substantial discretion in the ingredients to select, the formulation can be embodied by thousands of compositions.

[1] The Court's rule appears to be that concise statements of fact may only be 1750 words total, but L'Oréal's three opposition statements of fact total 3750 words (less than 1750 each). In order to respond, Plaintiffs have had to exceed a total of 1750 words, but have made every effort to keep their responses as concise as possible.

7	The independent claims of the patents-in-suit broadly cover adenosine compositions that, when topically applied, deliver adenosine to the dermal cells at the claimed concentrations. (Ex. A, claim 1; Ex. B, claim 1; Ex. U at 82:11-22.)	Undisputed that the independent claims of the patents-in-suit claim a "method comprising topically applying to the skin a composition comprising a concentration of adenosine in an amount effective to enhance the condition of the skin without increasing dermal cell proliferation, wherein the adenosine concentration applied to the dermal cells is 10^{-4} [or 10^{-3}] M to 10^{-7} M."
8	The patents-in-suit do not contain any working examples of formulations or compositions that, when topically applied, will reach the dermal cells at the claimed concentrations or enhance the condition of unbroken skin. (Ex. C, ¶ 271; Ex. A, *passim*; Ex. B, *passim*; Ex. U at 76:11-15, 78:14-19.)	Disputed. *See, e.g.*, Ex. A, at 4:51-5:11.
9	Many factors can influence the amount of a given compound, such as adenosine, that will reach "the dermal cells" following topical application. (*See* Ex. O at 95:13-24 ("[Q.] How much adenosine in a composition reaches the dermal cell layer? A. It depends on a lot of things. It depends on the concentration of adenosine in the composition. It depends on the penetrating agent used. It depends on the whole formulation and the interaction between the penetrating agents, adenosine, and all the things in the base. It's very, very dependent on all those factors working appropriately."); Ex. C, ¶ 272.)	Undisputed.

10	The specification of the patents-in-suit does not describe how to account for the factors that can affect how much adenosine will reach the dermal cells following topical application. (Ex. C, ¶ 272; Ex. A; Ex. B.)	Disputed. *See, e.g.*, Ex. A, at 5:9-24.
11	There is no description in the specification of the patents-in-suit of the claimed adenosine concentrations being obtained *in vivo* following topical application. (Ex. C, ¶¶ 265-66; Ex. A; Ex. B; Ex. U at 63:22-64:2.)	Undisputed that the specification of the patents-in-suit does not describe results from *in vivo* testing. L'Oréal's inferences are disputed.
12	There is no description in the specification of the patents-in-suit of an actual composition that was topically applied or that would deliver adenosine "to the dermal cells" in the claimed concentrations. (Ex. C, ¶ 265; Ex. A; Ex. B; Ex. O at 146:5-14 ("[Q.] In the '327 and '513 patents, you do not provide any examples of actual formulations containing adenosine; correct? A. Correct. Q. Okay. And in the '327 and '513 patents, you do not provide a specific list of ingredients that should be used when making formulations containing adenosine in order to achieve the claimed concentrations at the dermal layer; correct? A. That's correct".).)	Disputed. *See, e.g.*, Ex. A, at 4:51-5:24.

13	The specification of the patents-in-suit does not provide any guidance on how much adenosine needs to be in the composition to reach the dermal cells at the claimed concentration following topical application. (Ex. O at 242:5-11 ("Q. Do you provide any guidance in your patent to allow someone to determine how much adenosine they need to have in the composition in order to reach the concentrations of 10 to the minus 7 to 10 to the minus 4 molar at the dermal layer? A. We do not. It's up to – it's up to the reader".); *id.* at 175:7-13, 175:19-22; Ex. C, ¶ 272.)	Disputed. *See, e.g.*, Ex. A, at 4:51-5:43.
14	The specification of the patents-in-suit does not show that topical application of adenosine reduces "wrinkling, roughness, dryness, or laxity of the skin" or "enhance[s] the condition of the skin," as recited by the claims. (Ex. C, ¶ 268; Ex. U at 67:18-68:14.)	Disputed. *See, e.g.*, Ex. A, at 1:28-41, 3:23-40, 6:17-9:51.
15	The specification of the patents-in-suit contains only data from *in vitro* cell culture experiments involving isolated fibroblasts in which DNA synthesis, protein synthesis, and cell size data were reported, and not any *in vivo* or clinical data. (Ex. A, 6:15-9:50; Ex. C, ¶ 268; Ex. U at 61:19-23.)	Undisputed that the specification of the patents-in-suit does not report *in vivo* or clinical data. L'Oréal's inferences are disputed.

16	The specification of the patents-in-suit does not correlate the *in vitro* data with any particular outcome, be it general enhancement of skin condition or a reduction of one of the parameters referred to in the claims. (Ex. A, 6:15-9:50; Ex. C, ¶ 268.)	Disputed. *See, e.g.*, Ex. A, at 1:28-41, 3:23-40, 6:17-9:51.

DATED: October 16, 2020

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CERTIFICATION OF COMPLIANCE

The foregoing document complies with the type-volume limitation of this Court's March 2, 2020 form Scheduling Order For All Cases where Infringement is Alleged. The text of this brief, including footnotes, was prepared in Times New Roman, 14 point. According to the word processing system used to prepare it, the brief contains 241 words, excluding the case caption, signature block, table of contents and table of authorities.

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